K100653

510k Summary

OCT 8 2010

Prepared: July 21, 2010

Submitted By:
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Device Name: Denture relining, repairing, or rebasing resin
Trade Name: Jet XR
Common Name: Radiopaque Acrylic Resin
Classification Name: Dental Product
Classification: Class II
Product Code: EBI

Predicate: OrthoJet Acrylic Resin (manufactured by Lang Dental Manufacturing Co., Inc., a post-amendment device, K941925
Predicate Description: Intended for the fabrication of removable orthodontic PMMA appliances.

Statement of Intended Use: *Jet XR Radiopaque Acrylic Resin is intended for the fabrication of methacrylate-based acrylic appliances and used wherever a radiopaque acrylic dental device is useful in establishing an anatomical location or site, such as a provisional implant stent.*

Technological Characteristics:

Summary of Similarities: Jet XR and OrthoJet are of exactly the same methyl Methacrylate resin compound.

Summary of Dissimilarities: Jet XR has added to the OrthoJet compound Barium Sulfate in two variant concentrations to provide radiopacity in two separate levels to accomplish the diagnostic benefit

Performance Data:

Non-Clinical Data Submitted and Referenced:

Physical property tests were conducted in a laboratory setting to test for adequate flexural strength and modulus as well as sorption and solubility as has been practice with other provisional acrylic products even though no ISO or ADA standards exist for provisional restorative or diagnostic products. Given that this product is not under stress in provisional or diagnostic applications, the performance characteristics appeared adequate.

Clinical Data Submitted and Referenced:

No clinical data was submitted as the chemical composition was identical to the predicate product excepting the addition of Barium Sulfate which has established biocompatibility.

Conclusion that data demonstrates SE:

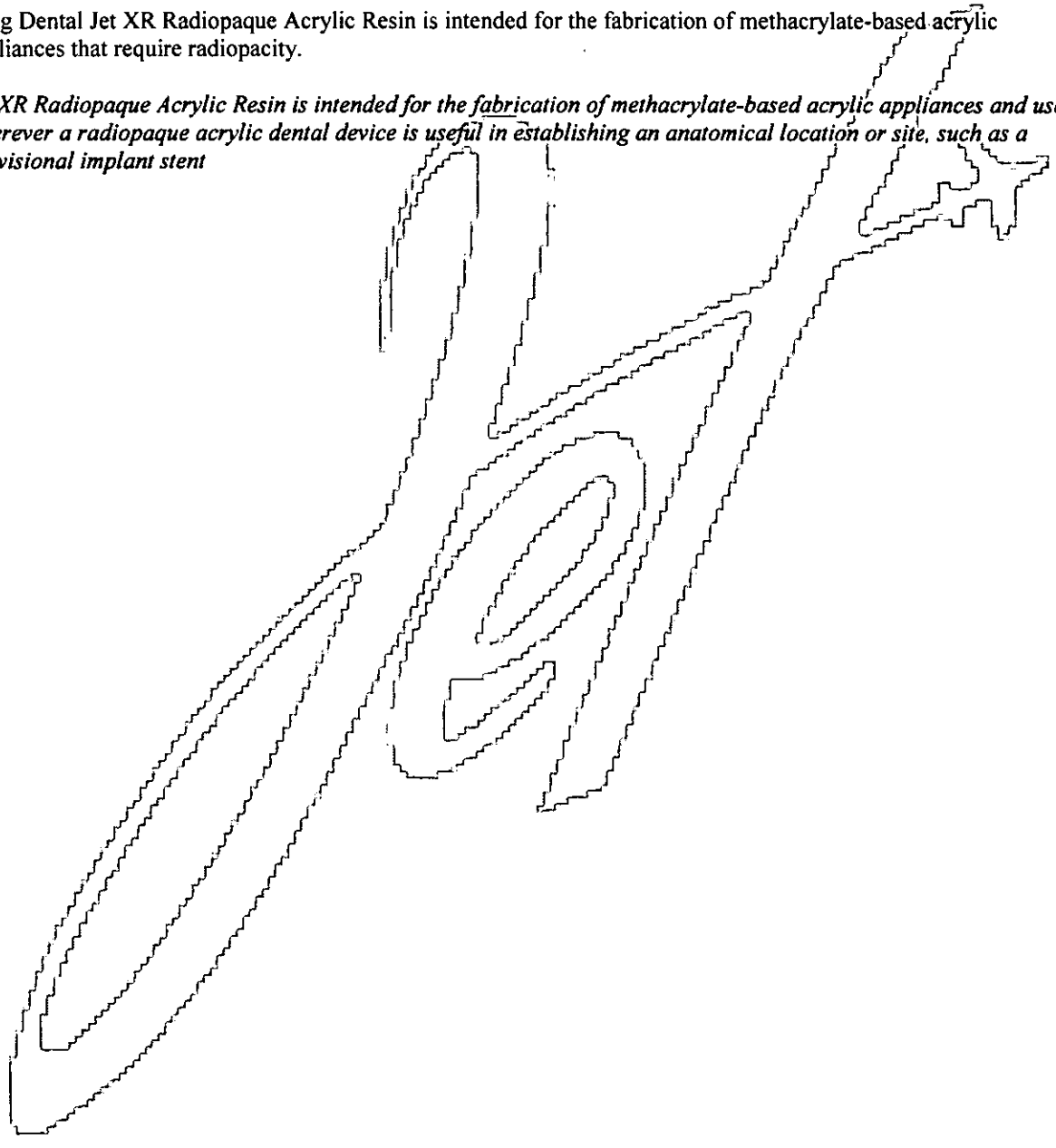
As the product is designed for diagnostic purposes and because it is of identical chemical composition to the predicate product except for the addition of the biocompatible radiopaque Barium Sulfate, this product is substantially equivalent.

PRODUCT DESCRIPTION

Lang Dental Jet XR Radiopaque Acrylic Resin is a high quality self curing 2-part system. The system is formed by a powder polymer and liquid monomer. The combination of powder polymer and liquid monomer is converted into a hard methacrylate finished product.

Lang Dental Jet XR Radiopaque Acrylic Resin is intended for the fabrication of methacrylate-based acrylic appliances that require radiopacity.

Jet XR Radiopaque Acrylic Resin is intended for the fabrication of methacrylate-based acrylic appliances and used wherever a radiopaque acrylic dental device is useful in establishing an anatomical location or site, such as a provisional implant stent



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Mr. David Lang
President
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Wheeling, Illinois 60090-0969

OCT 8 2010

Re: K100653
Trade/Device Name: Lang Dental Jet XR Radiopaque Acrylic Resin
Regulation Number: 21 CFR 872.3760
Regulation Name: Denture Relining, Repairing, or Rebasing Resin
Regulatory Class: II
Product Code: EBI
Dated: September 27, 2010
Received: September 29, 2010

Dear Mr. Lang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

fo

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K100653

Device Name: Lang Dental Jet XR Radiopaque Acrylic Resin

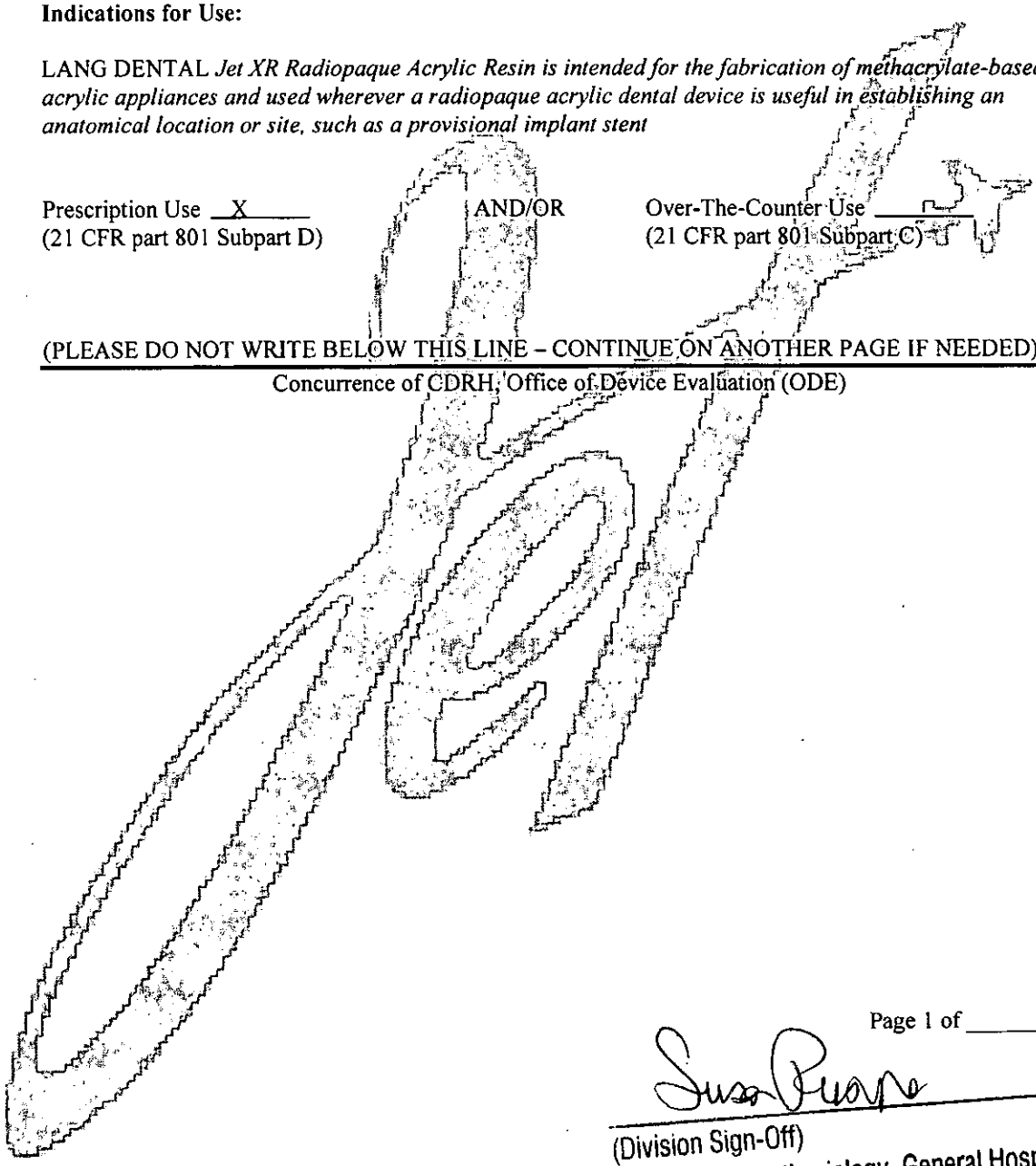
Indications for Use:

LANG DENTAL *Jet XR Radiopaque Acrylic Resin is intended for the fabrication of methacrylate-based acrylic appliances and used wherever a radiopaque acrylic dental device is useful in establishing an anatomical location or site, such as a provisional implant stent*

Prescription Use __X__ (21 CFR part 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices